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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,737	06/04/2001	Haifan Lin	180/104/2	6886

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/02/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/873,737

Applicant(s)

LIN, HAIFAN

Examiner

Dave Nguyen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-98 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, 45, drawn to an enormous number of biologically active *piwi* family polypeptides, classifiable in class 530, subclass 350.

Group II. Claims 14-29, 49, drawn to an enormous number of nucleic acid sequences encoding a biologically active *piwi* family polypeptide, vectors, host cells, and method of using the nucleic acid to make a polypeptide, classifiable in Class 536, subclass 23.5; and Class 435, subclasses 325 and 320.1.

Group III. Claims 6-13, 31-34, 38-43, drawn to an enormous number of antibodies capable of specifically binding to any biologically active *piwi* family polypeptide as recited in claim 1 drawn to an isolated YAP polypeptide classified in 530, subclass 387.9, for example.

Group IV. Claims 30, 36, 37, 44, drawn to a RNA or DNA binding assay, and kits used in the assay, classifiable in class 435, subclass 6, class 536, subclass 24.31.

Group V. Claims 35, drawn to an antibody binding assay, classifiable in class 435, subclass 7.1.

Group VI. Claims 46-48, drawn to a screening assay for any candidate compound including a polypeptide and/or gene encoding the polypeptide, classifiable in class 435, subclass 7.1.

Group VII. Claims 50-52, 55-60 drawn to a disease treatment method of employing an antisense, classifiable in class 514, subclass 44, class 536, subclass 24.5.

Group VIII. Claims 50, and 53-58, 61, 62, drawn to a disease treatment method of employing an antibody molecule, classifiable in class 424, subclass 130.1.

Group IX. Claims 63-65, 88-91, drawn to a protein therapy method and pharmaceutical compositions comprising a therapeutic protein, classifiable in class 514, subclass 2.

Group X. Claims 66-68, 92-98, drawn to a disease treatment method of employing a therapeutic DNA, and pharmaceutical composition comprising a therapeutic DNA vector, classifiable in class 514, subclass 44.

Group XI. Claims 69-75, drawn to a method of culturing a primitive cell, wherein a feeder matrix is

employed, classifiable in class 435, subclasses 69.1, 325.

Group XII. Claims 76-87, drawn to a method of making an embryo so as to alter a phenotype, transgenic animals, and methods of producing a protein in the animals, classifiable in class 800, subclasses 3, 4, and 8.

**Should any of the above group be elected, a further GROUP RESTRICTION is required with respect to multiple distinct and/or polypeptides or nucleic acid sequences encoding the polypeptides being claimed in claim 1.**

The multiple distinct and/or polypeptides or nucleic acid sequences encoding the polypeptides are as follows:

A/ SEQ ID NOS: 2 (polypeptide) or SEQ ID NO: 1 (DNA), sequences having 75% or greater homology, and sequences that hybridize to the DNA under the recited hybridization conditions.

B/ SEQ ID NOS: 4(polypeptide) or SEQ ID NO: 3 (DNA), sequences having 75% or greater homology, and sequences that hybridize to the DNA under the recited hybridization conditions.

C/ SEQ ID NOS: 6 (polypeptide) or SEQ ID NO: 15 (DNA), sequences having 75% or greater homology, and sequences that hybridize to the DNA under the recited hybridization conditions.

D/ a polypeptide which is a biological functional equivalent of a peptide as set forth in SEQ ID NO:  
2.

E/ a polypeptide which is a biological functional equivalent of a peptide as set forth in SEQ ID NO:  
4.

F/ a polypeptide which is a biological functional equivalent of a peptide as set forth in SEQ ID NO:  
6.

G/ A polypeptide which is immunologically cross-reactive with antibodies which are immunologically reactive with peptides encoded by the nucleic acid sequences as set forth in SEQ ID NO: 2.

H/ A polypeptide which is immunologically cross-reactive with antibodies which are immunologically reactive with peptides encoded by the nucleic acid sequences as set forth in SEQ ID NO: 4.

I/ A polypeptide which is immunologically cross-reactive with antibodies which are immunologically reactive with peptides encoded by the nucleic acid sequences as set forth in SEQ ID NO: 6.

J/ A polypeptide encoded by a DNA that hybridizes to fragments, or variants of SEQ ID NO: 1.

K/ A polypeptide encoded by a DNA that hybridizes to fragments, or variants of SEQ ID NO: 3.

L/ A polypeptide encoded by a DNA that hybridizes to fragments, or variants of SEQ ID NO: 5.

M/ A polypeptide comprising a portion of any of A/ to L/. Should M be elected, a further group restriction is required. Applicant is required to elected an invention that embraces a polypeptide comprising portion as set forth in A/ to L/.

The inventions are distinct, each from the other because of the following reasons:

With respect to the nucleic acid claims, the polypeptide claims, the antibody claims, the claims are directed to products that are distinct both physically and functionally, and are therefore patentably distinct; and are not required one for the other. For example, the polynucleotides are a fundamentally different type of molecule than the polypeptides as claimed, and the polynucleotides can be used other than to produce the claimed proteins, for instance, it can be used as a probe in nucleic acid hybridization. The proteins can be used for procedures other than the production of antibodies, such as in treatment of patients with the isolated protein. The polynucleotide or the polypeptides are also structurally and functionally distinct from the antibodies. Thus, these groups are directed to physically and functionally distinct elements, and are therefore patentably distinct; and are not required one for the other.

In addition, the DNA, polypeptide, or antibody is not limited for use in any particular method and can be used in different and distinct methods, as evidenced by the claimed methods as set forth in Groups IV-XII.

With respect the items (a)-(g) as set forth in claim 1, the species not only are written as improper members of a Markush Group, the species are structurally distinct among themselves, and each of which embraces an enormous number of DNA and/or protein sequences, which were claimed ambiguously or

broadly. As set forth in MPEP 803.02, unity of invention for exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Claim 1 does not have unity of invention because not only SEQ ID NO: 1, 3, and 5, or SEQ ID NOS 2, 4, 6 are structurally distinct, the breach of each of the item(s) as claimed is directed to an enormous number of sequences, which may not be overlapped with one another. As such, applicant is required to further elect a specific claimed invention as set forth in any of A/ to M/ for examination. Note also that due to limited resources from the US PTO and the breadth of the claims, it would be an undue burden on the examiner and the US PTO to search and examine of all the claimed subject matters as presently claimed.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions IV-XII constitutes patentably distinct inventions for the following reasons: Groups IV-XII are patentably distinct because they are directed to different classes, subclasses, and materially different methods, as indicated above.

Note that claims 50, 51, 55-58 link inventions VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 50, 51, 55-58. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper, particularly in view of an undue burden to search and examine of all of the presently pending claims.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. ' 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. ' 1.48(b) and by the fee required under 37 C.F.R. ' 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen  
Primary Examiner  
Art Unit: 1632

  
DAVE T. NGUYEN  
PRIMARY EXAMINER